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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,155	02/18/2004	Samir Mitragotri	LA-1279-385US	5021

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/782,155	Applicant(s) MITRAGOTRI ET AL.	
	Examiner Isis A. Ghali	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 11/01/2007.

Claims 1-3 have been pending and, claims 4-12 have been added.

Claims 1-12 are included in the prosecution.

The following new ground of rejection is necessitated by applicants' amendment:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims as amended as well as the newly added claims have introduced new matter that is not described in the specification as originally filed. Regarding claims 1 and 2, the limitation of "plurality of sharp hydration

gradients are created along the peripheries of the reservoirs" is not described anywhere in the specification even in the paragraphs applicants are referring to for support.

Claims 4 and 9 recite contact area "less than 1 cm²", and nowhere in the specification applicants had disclosed such an area. Additionally, claims 7 and 12 recites that "the inert material is air, and with careful recourse to the specification no support for this limitation has been found. In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

The following rejections have been discussed in the previous office action, and are maintained for reasons of record:

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,562,743 ('743).

US '743 disclosed transdermal drug delivery system to deliver active agents to the skin comprising multiple drug reservoirs separated from each other in a matrix layer (abstract; col.9, lines 57-65). Figure 5 shows that the contact skin is divided by smaller areas by the presence of the reservoirs, and the air containing space (36) extends to surround the drug containing areas.

5. Claims 1-12 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2005/0147654 ('654).

US '654 disclosed transdermal drug delivery system to deliver active agents to the skin comprising multiple channels loaded with drug and acts as reservoirs separated from each other in a matrix layer (abstract; paragraphs 0023, 0039, 0047). Figure 3 shows that the contact skin is divided by smaller areas by the presence of the channels. The channels are empty except for the drugs passing to the skin.

Response to Arguments

6. Applicant's arguments filed 11/01/2007 have been fully considered but they are not persuasive. Applicants argue that both prior art devices are incapable of forming such sharp hydration gradients because their reservoir walls are made of absorbent material (i.e., both Turner and Matloub) and/or the material surrounding the reservoirs are made of an adhesive permeable material. Thus, a sharp hydration gradient is formed at the interface of the skin areas that contacts the formulation. Applicants argue that Turner discloses multiple embodiments. Embodiments in Fig. 1,2, 3, 16 and 17 do

not disclose "a plurality of reservoirs" as required by Applicants claims. These embodiments show only one reservoir 16, and therefore do not anticipate. The remaining embodiments in Turner's Fig. 4-15, however, are not capable of providing the "sharp hydration gradients along the peripheries of the reservoir" as required by the present claims because hydration gradients cannot be formed because the wall/material immediately surrounding these absorbent reservoir and bodies are made of an adhesive material 18. Matloub the reservoirs are actual bodies 60 made of flexible foam material. Furthermore, between these reservoirs are microchannels 30, which are used to fill the reservoirs. Typically, when silicone is used as the polymer enrobing material, it will adhere to its skin surface because of its tacky nature. Accordingly, Matloub's reservoirs are not capable of forming a device "such that when the device is placed in contact with the skin of a recipient, a plurality of sharp hydration gradients are created" because the channels surrounding the reservoirs allow free passage of drug into the surrounding reservoirs. Claims 6 and 11 are also not anticipated by either Turner or Matloub. These claims are directed to embodiments where areas between the reservoirs are filled with an inert material. In contrast, in Turner's embodiments the areas between reservoirs are not inert but are made of adhesive material 18. In Matloub's embodiments the areas between the reservoirs are not inert but comprise of open channels 30. Claims 7 and 12 are also not anticipated by either Turner or Matloub. Claims 7 and 12 are directed to embodiments where areas between the reservoirs are left empty so that the skin is exposed only to air.

In response to these argument, applicants' attention is directed to the scope of the present claims that are directed to transdermal device comprising patch comprising reservoirs containing drug in a matrix (claim 1), and method of using the device comprising one step of applying the device in contact with the skin. It is well established that the claims are given the broadest interpretation during the examination. All the elements of the device are disclosed by both of cited references which are plurality of reservoirs containing the drug arranged in a matrix, and the function created by the reservoirs is inherent because the reservoirs containing the drug is surrounded by air in both references. The step of applying the device to the skin as recited by the method claims is also disclosed by both of the cited references. Figure 5 of Turner shows multiple reservoirs (42) separated by spaces filled with air extending from air space (36), see also col.9, lines 30-53. Matloub disclosed channels that contain air to separate the areas containing the drug, i.e. the reservoirs. The channels are empty except for the drug delivered to the skin. The references read on the claims in absence of specific structure of the reservoirs and the spaces. The claims' language does not exclude the presence of other layers such as the enrobing layer, adhesive in the device or active ingredients in the channels containing air. As such, it is the examiner's position that the product and method of its use advanced by the references anticipate the product and method enumerated in the instant claim set. It has been held that the failure of those skilled in the art to contemporaneously recognize an inherent property, function, or ingredient of a prior art reference does not preclude a finding of anticipation. Whether or not an element is inherent in the prior art is a fact question. Inherency is not

necessarily contemporaneous with knowledge of those of ordinary skill in the art, who may not recognize the inherent characteristics or functioning of the prior art. However the discovery of a previously unappreciated property of a prior art product does not render the old product new to the discoverer. See *Atlas Powder versus Ireco*, 51 USPQ 2d 1943, (Fed. Cir. 1999).

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,132,115 and US 4,834,978 both teach transdermal devices comprising microreservoirs containing therapeutic agents.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1611

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis A Ghali
Primary Examiner
Art Unit 1611



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ISIS GHALI
PRIMARY EXAMINER